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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/451,641	11/30/1999	Danchen Gao	PC10664	9327

28523 7590 05/27/2010

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PATENT DEPARTMENT
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EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1615	

NOTIFICATION DATE	DELIVERY MODE
05/27/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

~IPGSGro@pfizer.com

Office Action Summary	Application No.	Applicant(s)	
	09/451,641	GAO ET AL.	
	Examiner	Art Unit	
	S. TRAN	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 May 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,12-50,72-75,84 and 86-90* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,12-50,72-75,84 and 86-90* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 05/07/10 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10, 12-50, 72-75, 84 and 86-90 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. While page 22, lines 20-21 of the present specification discloses the use of hydroxypropylcellulose (HPC), the specification specifically teaches that such HPC is a binding agent particularly added for tablet formulations. See lines 10-11 of page 22. The examiner notes that claim 1 is not directed to a tablet formulation. More importantly, claim 1 does not require the present

of binding agent. This is evident by the limitation in claim 14, which recites that the composition *further* comprising binding agents. Accordingly, because claim 1 does not recite a tablet and binding agents as positive limitations, the claims cannot preclude the present of HPC.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 16 contains the trademark/trade name "Rexcel™". Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe the diluents and, accordingly, the identification/description is indefinite.

There is no description in the specification of the exact ingredients of "Rexcel™" which can change over time.

Claim 23 is rejected for failing to further limit the subject matter of claim 1. While claim 1 precludes the present of HPC, the binding agents recited in Claim 23 include HPC.

Claim Rejections - 35 USC § 103

Claims 1-10, 12-50, 72-75, 84 and 86-90 are rejected under 35 U.S.C. 103(a) as being unpatentable over Franson et al. US 5,591,456, in view of Black EP 0 863 134 and AAPS Annual Meeting Contributed Papers Abstracts (AAPS).

Franson teaches a dispersible particle comprising crystalline NSAID having hydroxypropyl cellulose adsorbed on the surface thereof in an amount sufficient to maintain an effective average particle size of less than about 1000 nm, and at least 99% of the particle has size less than 400 nm (abstract; and column 3, lines 56 through column 4, lines 1-4).

Franson does not teach the claimed NSAID compound, such as celecoxib.

Black teaches a compound useful as a Cox-2 inhibitor for pain relief, fever and inflammation of a variety symptoms disclosed on page 3, lines 29-36. The compound can be administered orally in the form of tablets, troches, lozenges, or capsules (page 4, lines 1-12). The tablets comprise active ingredient in admixture with excipients, *e.g.*, diluents, disintegrants, binding agents, wetting agents, and surfactant (page 4, lines 15-38). The active agent is present in an amount of 10 to 250 mg. The carrier material may vary from about 5 to about 95% (page 5, lines 39-58). The dosage can be

administered once or twice a day, and will provide effective $T_{1/2}$ over a 24 hours period (page 5, lines 22-27). Example 2 discloses the amount of excipients use in a tablet.

Thus, it would have been obvious for one of ordinary skill in the art to modify the NSAID formulation of Franson using the COX-2 compound of Black, because Black teaches a COX-2 compound that is proved useful as an alternative to conventional NSAIDs (page 3, lines 41-46), because Black teaches COX-2 as a partial or complete substitute for conventional NSAIDs, and because Franson teaches a particle dispersion suitable for a wide variety of active agents including a number of NSAIDs.

Franson further does not teach the claimed properties, such as bioavailability, C_{max}, and T_{max}.

AAPS teaches a celecoxib (Cox-2 inhibitor) formulation that exhibits an unchanged C_{max} value of 1527 and 1077 ng/mL, and a T_{max} of 1.9 hours (see page D32). At page 3469, the AAPS reference teaches a COX-2 composition that is rapidly absorbed with a T_{max} of 1.9 hours, and eliminated with a $t_{1/2}$ of about 15 hours. Accordingly, it would have been obvious to one of ordinary skill in the art to optimize the parameter of Franson in view of Black and AAPS to obtain the claimed properties. This is because AAPS teaches properties of a COX-2 formulation that is useful in pharmaceutical art.

Response to Arguments

Applicant's arguments filed 05/07/10 have been fully considered but they are not persuasive.

Applicant states that claims 16 and 29 have been amended to obviate the 112, second paragraph rejection.

However, it appears that the term "Rexcel™" in claim 16 was inadvertently left in the claim. Accordingly, the 112, second paragraph is maintained.

Applicant argues that the claimed celecoxib particles are not composite particles. Applicant states that the primary reference Franson et al., mandates a composite particle. This is a fundamental difference and it is clear from the quoted passages above from Applicants' specification that Applicants' particles, were they to be composite celecoxib particles, would not provide the advantages of Applicants' claimed composition because Applicants' claimed invention advantages are due at least in part to particulate nature of the celecoxib particles (vs. composite particles).

However, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the feature upon which applicant relies (i.e., celecoxib particles are not composite particles) is not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant argues that the present claims have been amended to preclude HPC.

However, although Franson teaches the use of HPC, the purpose of using HPC is to enhance resistant to gastric irritation. See column 3, lines 49-55. Accordingly, the

burden is shifted to applicant to show that the present of HPC would detrimentally affect the desirability for obtaining a composition having high bioavailability. It is of note that Franson teaches a composition that exhibits a high bioavailability. See example 1.

Accordingly, the 103(a) rejection of record is maintained.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to S. TRAN whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 8:30 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. TRAN/
Primary Examiner, Art Unit 1615